# UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

| UNITED STATES OF AMERICA, | ) |                       |
|---------------------------|---|-----------------------|
| Plaintiff,                | ) |                       |
| v.                        | ) | Case No. 19-CR-58-JED |
| GREGORY SINCLAIR CONNOR,  | ) |                       |
| Defendant.                | ) |                       |

#### **OPINION AND ORDER**

The Court has for its consideration the Motion of Defendant Gregory Sinclair Connor, who seeks to recover attorney's fees incurred while defending himself against the charges brought against him by the government. (*See* Doc. 134).

#### I. Background

Dr. Connor is a neurologist who, at the time relevant to this case, ran a small medical practice in Tulsa, Oklahoma. As part of his practice, Dr. Connor treated patients suffering from various nerve disorders using the medication popularly known as Botox. Many of these patients relied on Medicare for their health insurance, but the program's reimbursement rate for Botox was frequently less than the price charged by Allergan, the drug's manufacturer. After receiving advertisements from Canadian pharmacies offering Botox at a lower price, Dr. Connor began to use them when sourcing Botox treatments for Medicare patients. Although the Botox he ordered was genuine, it came from outside of the approved supply chain.

In connection with this conduct, the government charged Dr. Connor with 36 counts of health-care fraud in violation of 18 U.S.C. § 1347; one count of receiving a misbranded drug with the intent to defraud in violation of 21 U.S.C. §§ 331(c) and 333(a)(2); and four counts of

aggravated identity theft in violation of 18 U.S.C. § 1028A(a)(1). (See Second Superseding Indictment, Doc. 53).

Notably, the government did not allege that Dr. Connor's purchase of the drugs from Canada was illegal in and of itself or that he committed health-care fraud simply by billing Medicare for Botox obtained at a discount. Rather, all of the charges against Dr. Connor turned, to some degree, on the labeling and packaging of the Botox he purchased.

At trial, the government's case on the misbranding count was relatively straightforward. A constellation of statutes and regulations governs what information must be present on the labeling of any prescription drug, including Botox, and a drug is "misbranded" when its labeling lacks one or more of the required elements. *See* 21 U.S.C. § 352. At trial, Special Agent Daniel Allgeyer of the Food and Drug Administration testified that he and another agent visited Dr. Connor's office and seized multiple vials of Botox that appeared to be packaged for distribution abroad. Other FDA officials then testified that the boxes and package inserts accompanying the vials did indeed lack the necessary labeling.

The government's theory on the health-care fraud counts was significantly more complex. The central claim was that Dr. Connor engaged in a "scheme and artifice to defraud" wherein he knowingly billed Medicare for services that were not eligible for reimbursement. The Social Security Act, which governs the program, provides that "no payment may be made" for items and services except those that are "reasonable and necessary" for the diagnosis or treatment of some malady. 42 U.S.C. § 1395y(a)(1)(A). Medicare generally considers Botox to be reasonable and necessary for the conditions suffered by Dr. Connor's patients, but the government attempted to show that the Botox he used was nevertheless ineligible for reimbursement because it was not "approved" as that word is defined by the FDA.

To that end, the government offered the testimony of Dr. Arthur Simone, an FDA official, as an expert in the agency's approval process. According to Dr. Simone, the FDA does not approve "drugs per se"; rather, it approves "applications." (Doc. 145 at 89–91). And new-drug applications are evaluated not only for the risks and benefits associated with the drug itself but also for the labeling and packaging necessary to ensure the drug's safe and efficacious use. All prescription drugs are required to include on their labeling a National Drug Code (NDC), a 10-digit number assigned by the FDA that identifies the product and its maker. (*Id.* at 104). Thus, according to Dr. Simone, a drug is said to be "unapproved" when it has nonconforming labeling, even if studies have shown the drug itself (i.e., the chemical compound) to be safe and effective when properly used. Since the Botox seized from Dr. Connor's office lacked several elements of the approved packaging, including an NDC number, Dr. Simone opined that the seized vials could not qualify as Botox "approved for sale and use in the United States." (Doc. 145 at 118).

In order to connect the lack of FDA "approval" to the health-care fraud counts, the government presented the testimony of Dr. Kathryn Rankin, a consultant who investigates Medicare fraud for the government. According to Dr. Rankin, Medicare only considers a drug to be "reasonable and necessary" for reimbursement purposes if it is "safe and effective," and something is considered to be safe and effective only if it is approved by the FDA. (Doc. 146 at 150). She further testified that the Medicare billing code for Botox is linked to the NDC numbers that the FDA has assigned to the drug's various formulations, and that providers are not permitted to use the billing code unless the Botox in question has been given one of those NDC numbers. (Doc. 152).

Taken together, the testimony of Dr. Simone and Dr. Rankin was meant to show (1) that the Botox Dr. Connor ordered from Canada was not "FDA approved" because it did not have the

required labeling; (2) that Medicare only pays for drugs that are FDA approved; and (3) that, in light of propositions one and two, Dr. Connor was not entitled to bill Medicare for the Botox he bought from abroad, even if it was genuine Allergan product and chemically indistinguishable from Botox purchased through the domestic supply chain.

The government's case for aggravated identity theft was also counter intuitive. In order to prove identity theft, the government had to show that Dr. Connor used his patients' Medicare identification numbers "without lawful authority." 18 U.S.C. § 1347. At trial, the alleged victims testified that they gave Dr. Connor's office their Medicare information so he could bill them for the Botox treatments, but the government's case seems to have been that this did not qualify as "lawful authority" because he had not informed them that the treatments were not reimbursable under Medicare's rules.

The jurors were apparently unconvinced. After a four-day trial, they returned a verdict of not guilty on all counts. (Doc. 128).

#### II. Legal Standard

The text of the Hyde Amendment provides that attorney's fees and costs are available to a defendant when the district court finds the Government's position to have been "vexatious, frivolous, or in bad faith." Pub. L. 105–119, § 617, 111 Stat. 2440, 2519 (1997) (codified at 18 U.S.C. § 3006A note). The Tenth Circuit, reading these terms according to their "plain and ordinary meaning," gives them the following definitions: vexatious means "without reasonable or probable cause or excuse; harassing; annoying"; frivolous means "lacking a legal basis or legal merit; not serious; not reasonably purposeful"; and bad faith means "dishonesty of belief or purpose." *United States v. Lain*, 640 F.3d 1134, 1137 (10th Cir. 2011) (quoting Black's Law

<sup>1.</sup> Only two of the identity theft counts made it to the jury. The Court dismissed the others at the government's request prior to trial. (Doc. 96; Doc. 105).

Dictionary (8th ed. 2004)). The defendant bears the burden of proving one of these three grounds. *United States v. Manzo*, 712 F.3d 805, 810 (3d Cir. 2013); *see also Lain*, 640 F.3d at 1138 (holding that the defendant "failed to present clear evidence of vindictive prosecution").

#### III. Discussion

Dr. Connor points to a variety of reasons why, in his view, the government's position against him cannot be viewed as other than vexatious, frivolous, and in bad faith. Although his briefing is somewhat scattershot, his arguments seem to be (1) that government had little to no evidence to support essential elements of the alleged offenses; (2) that the government attempted to convict him for non-criminal conduct; (3) that the government falsely claimed that certain labeling elements were legally required; and (4) that the FDA engaged in misconduct during the investigation and at trial.

Having thoroughly reviewed the record, the Court concludes that Dr. Connor has not shown that the government's position was, in whole or in part, "vexatious, frivolous, or in bad faith." This is not to say that the government's conduct was exemplary or that its evidence put Dr. Connor's guilt beyond a reasonable doubt. On the contrary, several aspects of the government's investigation and prosecution of this case give cause for concern. Still, for the reasons explained below, the government's position was not so egregious as to rise to the level of a compensable violation of the Hyde Amendment.

#### A. Lack of Evidence

Dr. Connor contends that the government had little or no evidence to support the charges against him, but his arguments misstate the record. For example, he claims that he could not have been guilty of the alleged scheme because the evidence showed that his assistant, Judy Hurst, is the one who ordered the Botox and billed the treatments to Medicare. This, however, ignores the fact that the evidence also showed that Ms. Hurst was acting at all times with Dr. Connor's

knowledge and approval, and that Dr. Connor participated in the decision to source Botox for Medicare patients from a Canadian pharmacy.

Similarly, Dr. Connor complains that the government had no evidence that the Botox he billed to Medicare was labeled other than as required by the FDA because the vials and packaging for those orders had long ago been discarded. The only vials that the FDA actually inspected were the ones seized from his office, and he never administered those doses or billed them to the program. Consequently, he argues, the government could never have proved that he impermissibly billed Medicare for "unapproved" Botox. Again, Dr. Connor distorts the record.

It is not disputed (1) that Dr. Connor's office had, for several years, sourced all Botox for Medicare patients from a single Canadian pharmacy; (2) that Allergan labels its drugs differently depending on the market where they are to be distributed; and (3) that all seven of the seized vials, which were ordered from the Canadian pharmacy, lacked several of the elements that the FDA requires in order for Botox to qualify as "approved." Thus, while the government did not have physical evidence that the billed-for Botox lacked the required FDA labeling, there was substantial circumstantial evidence to that effect.

This is not to say that the government's case was strong. In order to prove health-care fraud, the government was required to show that Dr. Connor acted "knowingly and willfully." 18 U.S.C. § 1347(a). While this did not require proof that Dr. Connor had actual knowledge of the health-care fraud statute, *see* 18 U.S.C. § 1347(b), it did require him to know that his conduct was unlawful, *see United States v. Franklin-El*, 554 F.3d 903, 908 (10th Cir. 2009); *United States v. Rufai*, 732 F.3d 1175, 1190 (10th Cir. 2013).

The government's rather abstruse theory of health-care fraud made it difficult to prove the requisite degree of mens rea. In a garden variety health-care fraud case, the scheme itself provides

an inference of the defendant's guilty mind. When a doctor bills Medicare for drugs he never bought or treatments he never administered, it is reasonable to conclude that he knows his conduct is wrongful, whether or not he is familiar with 18 U.S.C. § 1347 or the minutia of Medicare's byzantine billing rules. Here, however, the essence of the government's case was not that Dr. Connor billed for sham Botox or fictitious treatments; it was that he billed Medicare for Botox that, though genuine and used to provide real relief to real patients, was nevertheless not eligible for reimbursement because its labeling lacked some of the elements required by the FDA. Merely explaining why the same drug is eligible when packaged in one box but not eligible when packaged in another, nearly identical, box required the expert testimony of multiple government bureaucrats.

Still, the government did have some circumstantial evidence of Dr. Connor's knowledge and intent. For example, Dr. Connor knew that Medicare's reimbursement rate for Botox far exceeded the prices he was paying to the Canadian pharmacy. Given the disparity, one could reasonably conclude that a person of Dr. Connor's education would have wondered whether Medicare intended to reimburse for drugs purchased at a discount from abroad. From this, one could reasonably infer that Dr. Connor never asked Medicare for guidance because he knew that the answer was no.

Dr. Connor's interactions with the FDA were also not entirely consistent with those of a person who had nothing to hide. When Agent Allgeyer asked to see some of Dr. Connor's Botox, Dr. Connor initially retrieved a vial purchased for a patient whose private insurer required Dr. Connor's office to source the drug from Allergan's domestic supplier. Because the vial was packaged for distribution in the United States, it bore all the required labeling. Connor's assistant later revealed that there were seven other vials in the refrigerator. All were purchased from the Canadian pharmacy for use on Medicare patients. None were labeled as required. Was it a

coincidence that, of the eight vials he had on hand, Dr. Connor initially retrieved the only vial that would not incriminate him? Maybe, but the odds suggest otherwise.

#### **B.** Prosecution for Noncriminal Conduct

Dr. Connor further argues that the government, by prosecuting him, attempted to elevate a breach of administrative rules to the status of criminal conduct. As evidence, he points to the testimony of Dr. Rankin, the government's Medicare billing expert. At trial, Dr. Rankin testified that providers bill drugs to Medicare using "J-codes" and that every J-code has an NDC number associated with it. (Doc. 146 at 152). Consequently, she said, "the product that you're using must have an NDC code in order for you to bill Medicare because you need to use a J-code to bill Medicare. So no NDC code, no J-code, no bill to Medicare." (*Id.*). "If you don't have FDA-approved NDC code, you cannot properly bill [the Botox J-code], so you're submitting a false claim to the government for payment." (*Id.* at 159).

According to Dr. Connor, Dr. Rankin's testimony amounts to a claim that a provider necessarily commits health-care fraud if he bills Medicare for drugs without an NDC number. In doing so, he argues, the government sought to transform health-care fraud into a strict-liability offense. This argument has no merit.

As the government explains in its response, the purpose of this portion of Dr. Rankin's testimony was to establish the first element of health-care fraud: a scheme to "obtain a health care benefit program's money or property through materially false pretenses, representations, or promises." (Doc. 148 at 15–16). In other words, her testimony was offered as evidence that, by filing claims under the J-code for Botox, Dr. Connor made false representations to Medicare.

The government never denied that establishing health-care fraud required proof that Dr. Connor acted with the specific intent to defraud. To the extent Dr. Connor felt that Dr. Rankin's testimony implied that Dr. Connor must have known that he was not supposed to bill the J-code

unless he was using Botox with a corresponding NDC code, he could have undermined the inference of ill intent on cross examination. For example, Dr. Connor could have asked Dr. Rankin why a doctor, faced with two nearly identical boxes of Botox, should be expected to know that Medicare only reimburses for the Botox whose packaging has a particular number printed on the side. Similarly, Dr. Connor might have pointed out that NDC numbers are standard across products, so a doctor who habitually uses the same drug would have no practical reason to look for the number every time he dispenses it.

In short, the government's case did not rely on a strict-liability theory of health-care fraud; it merely alleged a scheme whose underlying illegality rested on hyper-technical Medicare billing rules. Indeed, it may have been the esoteric nature of the rules that led the jury to acquit Dr. Connor. Nonetheless, a prosecution does not become "vexatious, frivolous, or in bad faith" merely because the underlying theory is hard to explain.

### C. The Government's "Ever-Changing Theory" of Incorrect Labeling

Dr. Connor spills much ink discussing the government's "Ever Changing Theory of Correct/Incorrect Labeling," but the argument is so poorly explained and rife with citation errors that the Court is not entirely sure of its point. (*See* Doc. 134 at 8–10). To the extent the Court has followed the plot, the argument seems to be that, although the government made much of the fact that the Botox seized from his office did not bear the word "OnabotulinumtoxinA" on its labeling, the government never established that this was a legal requirement. If indeed this is the argument that Dr. Connor seeks to advance, he overstates his case. The government claimed that the labeling was missing several elements required for Botox to be "approved" for distribution and use in the United States. "OnabotulinumtoxinA" was only one of them. Thus, even if OnabotulinumtoxinA was not legally required, other labeling deficiencies existed to support the charges in question.

## D. Alleged Investigatory Misconduct

Dr. Connor also contends that Special Agent Allgeyer engaged in illegal subterfuge during the investigation and then lied about it in court so the evidence he gathered could be used at trial. Although some of these concerns are valid, nothing about Agent Allgeyer's conduct suggests that the government unfairly targeted Dr. Connor or brought the charges against him in bad faith.

Much of the government's evidence against Dr. Connor stemmed from the initial interaction that he and his assistant had with FDA investigators at Dr. Connor's practice. Before trial, Dr. Connor attempted to have the evidence suppressed on the grounds that Special Agent Allgeyer tricked him and Ms. Hurst into answering questions and providing him access to inculpatory evidence, such as the imported Botox found in Dr. Connor's refrigerator. During a pretrial hearing to determine the admissibility of the evidence, Connor and Hurst testified that Allgeyer told them that he was looking into illegal Canadian pharmacies and wanted them to help with the investigation. Dr. Connor, in testimony later echoed by Ms. Hurst at trial, said that the agents went so far as to ask them to participate in a "sting" operation by ordering more Botox from the Canadian pharmacy through its online portal. This was at least partially corroborated by Allgeyer's notes, which indicated that Ms. Hurst gave him her login credentials for the website. Hurst and Connor said that, because they thought that the agents only wanted their help in bringing down an illicit pharmacy operation, they fully cooperated, answering questions about their billing practices and granting the agents access to the office's records and Botox stores.

After Agent Allgeyer had what he needed, he presented Dr. Connor with a waiver form saying that he had consented to the search. Although the form indicated that Dr. Connor had been informed of his right to refuse prior to giving his consent, that was not true. As Agent Allgeyer later admitted, nobody told Dr. Connor he could refuse the agents' request until they handed him the form. By then, the search had already been completed.

Allgeyer's testimony on these issues was, at best, murky. On direct examination, the government asked Agent Allgeyer, "[D]id you lie about anything or deliberately mislead [Connor and Hurst] in any fashion?" to which he responded, "No." (Doc. 79 at 51). On cross examination, however, he was more equivocal:

- Q. Now, when you talked to Dr. Connor, you told him about an investigation you were doing on a Canadian pharmacy, didn't you?
- A. I believe I indicated that -- yes, we received information that sometimes some doctors receive these medications from what with they believe is a Canadian pharmacy.
- Q. And you wanted Dr. Connor's help, didn't you?
- A. Possibly.
- Q. Well, not possibly, you asked him to help with the investigation of the Canadian pharmacy, didn't you?
- A. I don't remember.
- Q. You asked him to order drugs from a Canadian pharmacy so you could help prosecute them, didn't you?
- A. I don't believe I did.
- Q. In fact, you asked him to participate in a sting operation for a Canadian pharmacy, didn't you?
- A. Doesn't sound likely. I don't remember that at all during our conversation.

(Doc. 79 at 64).

Several aspects of Agent Allgeyer's conduct are troubling. First, Agent Allgeyer clearly engaged in some skulduggery in order to get Dr. Connor talking and gain access to his Botox supply. This may have been permissible under the constitution, *see United States v. Harrison*, 639 F.3d 1273, 1280 (10th Cir. 2011), but what is permissible is not always wise. Law enforcement cannot function without the cooperation of the public. If investigators routinely request such cooperation merely as a ploy, even innocent people might refuse to cooperate out of fear that they will unwittingly incriminate themselves.

Second, Agent Allgeyer was less than forthright with the Court when testifying about the manner in which he gained Dr. Connor's confidence and, by extension, the incriminating evidence.

Although he initially testified that he did not intentionally deceive Dr. Connor, he later admitted

to telling Dr. Connor that the FDA was investigating Canadian pharmacies. While possibly true in the technical sense that the FDA does investigate Canadian pharmacies, this was almost certainly calculated to give Dr. Connor the false impression that he was not the investigation's primary target. At the very least, his use of the waiver form was deceptive because it implied that Dr. Connor had given his *informed* consent to the search when this was not the case.

That being said, Allgeyer's conduct, when viewed against the record as a whole, is not sufficient to show that the government's case against Dr. Connor was in bad faith. For one, Agent Allgeyer's lack of candor on the stand had no bearing on the case. As the Court explained in its opinion denying Dr. Connor's motion to suppress, even if Agent Allgeyer engaged in exactly the kind of subterfuge alleged by Dr. Connor and Ms. Hurst, that would not render their consent constitutionally infirm. (Doc. 95 at 11–15). For another, contrary to Dr. Connor's assertion, it is far from clear that Allgeyer perjured himself. Perjury, under the federal statute and at common law, requires literal falsity. *See Bronston v. United States*, 409 U.S. 352, 357–59 (1973). Here, the record is not sufficient to show that any of the statements transcribed above were literally untrue. Allgeyer's claim that he did not "lie about anything or intentionally mislead" Connor and Hurst is at odds with their descriptions of events, and, to a certain degree, with his own testimony on cross examination, but contradictions and changes in a witness's testimony alone do not constitute perjury, *Tapia v. Tansy*, 926 F.2d 1554, 1563 (10th Cir. 1991).

In any case, the Court need not reach the question of whether Allgeyer perjured himself. It is axiomatic that the government cannot be said to have acted in bad faith in presenting Allgeyer's testimony unless the government knew that he was testifying falsely, yet Connor points to no evidence that it did. Thus, Allgeyer's seeming lack of candor with the Court, while troubling, does not entitle Dr. Connor to recovery under the Hyde Amendment.

## E. Other Arguments

In addition to the arguments summarized above, Dr. Connor points to eight pretrial motions in which he argued various grounds for dismissing the indictment or suppressing evidence against him. Although the Court overruled those motions, Dr. Connor "reurges those motions now and argues they prove how the Government's prosecution of Dr. Connor was frivolous, vexatious and/or in bad faith." (Doc. 134 at 16).

Dr. Connor's effort to revive the previously rejected arguments is too poorly developed to qualify as raising a genuine issue requiring the Court's attention. He does nothing to connect the arguments to the Hyde Amendment standard or explain why the Court was in error when it rejected those arguments the first time. Accordingly, the Court simply refers him to its prior opinions in this case.

## F. Application to the Hyde Amendment Standards

In sum, the Court finds that Dr. Connor did not satisfy his burden to show that the government's position was "vexatious, frivolous, or in bad faith" as the Tenth Circuit has defined those terms. The government's position, for all its weaknesses, was not "vexatious" in the sense that the prosecution was "without reasonable or probable cause or excuse." The FDA began investigating him after customs officials intercepted a shipment of Botox at the border, bound for his office. Further investigation yielded evidence that Dr. Connor had indeed been importing the drug from abroad for years and billing the associated treatments to Medicare, even though the program does not reimburse for drugs unless they, and their labeling, have been approved by the FDA. Because there was some evidence that Dr. Connor knew he was not supposed to be billing for the discounted Botox, the government had probable cause to bring the charges against him.

Similarly, the evidence does not support a finding that the government was vexatious in the sense that it pursued Dr. Connor merely for the purpose of "harassing" or "annoying" him. As explained by the FDA officials who testified at trial, Botox packaged for sale abroad does not include many of the labeling elements that the FDA has deemed to be necessary for the drug's safe and efficacious use. Prosecuting doctors who import Botox of this kind therefore serves a legitimate public safety interest by discouraging others from doing likewise. Arguably this interest could be better served by educating doctors about Medicare's billing rules and the dangers of importing drugs from abroad, but that is a policy decision best left to other branches of government.

Dr. Connor has also failed to show that the government's position was frivolous in the sense of "lacking a legal basis or legal merit," "not serious," or "not reasonably purposeful." The misbranding charge was clearly legally sound, and, although the theory underpinning the health-care fraud charges was somewhat strained, they too had a reasonable legal foundation. Even the identity theft charges, which the Court views as the weakest of the bunch, were not without some basis in the law.<sup>2</sup>

Finally, there is no evidence that the government acted with "dishonesty of belief or purpose" in pursuing Dr. Connor. As explained above, the government did have probable cause to pursue the charges against him, and Dr. Connor has presented no evidence that the government did not genuinely believe that he was guilty. Accordingly, he has not shown that the government's position was taken in bad faith.

<sup>2.</sup> Although Dr. Connor does not specifically point to the identity-theft charges as grounds for recovery under the Hyde Amendment, the government's theory rested on a tenuously broad reading of the statute. A person commits the offense of aggravated identity theft when he "knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person" in connection with certain enumerated felonies. 18 U.S.C. § 1028A(a)(1). Several circuits have rejected identity theft charges in cases where the "use" of the victim's identity did not involve any attempt by the defendant to pass himself off as the victim. *See United States v. Berroa*, 856 F.3d 141, 155–57 (1st Cir., 2017) *United States v. Hong*, 938 F.3d 1040, 1049–51 (9th Cir., 2019); *United States v. Medlock*, 792 F.3d 700 (6th Cir. 2015). Here, there is no evidence that Dr. Connor attempted to pass himself off as his patients by billing their treatments to Medicare.

# IV Conclusion

For the reasons explained above, the Court finds that Dr. Connor has not shown the government's position in this matter to have been vexatious, frivolous, or in bad faith. The Court therefore **denies** his motion to recover under the Hyde Amendment (Doc. 134).

SO ORDERED this 8th day of March, 2021.

JOHN E. DOWDELL, CHIEF JUDGE UNITED STATES DISTRICT COURT